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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,063	08/23/2001	Michael R. Dupelle	04644-101001	1672
26161	7590	11/04/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			DROESCH, KRISTEN L	
		ART UNIT	PAPER NUMBER	
		3762		

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/938,063	DUPELLE ET AL.
	Examiner	Art Unit
	Kristen L Drosch	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 22 September 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 11-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-17 and 19-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 August 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: SKIN APPLIED ELECTRODE PADS HAVING U-SHAPED RELEASE SHEETS

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11- 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: each electrode comprising an adhesive, thus necessitating the use of the language “each adhesive” and “each release sheet”.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner et al. (6,178,357) in view of Ferrari (5,571,165) and further in view of Smith Ind. Pub. Lim. Co., (EPO 434258 A2). Gliner et al. shows a defibrillator comprising a defibrillator control box; a pair of mechanically integrally connected electrode pads (20); leads (16) connecting the electrode pads to the defibrillator control box; each electrode pad comprises an electrode sized and configured for defibrillation; an adhesive configured to adhere the defibrillation electrode to a patient's skin and at least two electrode release sheets (42) one on each of the electrode pads (Col. 4, lines 1-36).

Although Gliner et al. fails to specifically point out that the electrode pads have a skin contacting area of at least 50 centimeters squared, attention is directed to Ferrari which teaches that the ANSI/AAMI (American National Standards Institute/ Association for the Advancement of Medical Instrumentation) specifies the minimum active area of individual self adhesive electrodes used for adult defibrillation should be at least 50 centimeters squared (Col. 1, lines 19-28). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to size the defibrillation electrodes of Gliner et al. to have an active area of at least 50 square centimeters in order to comply with industry standards for the minimum active area of individual defibrillation electrodes.

Although Gliner et al. and Ferrari fail to show a first portion of the release sheet covering the adhesive and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad while the electrode pad is held in a desired location, attention is directed to Smith Ind. Pub. Lim. Co., which shows an adhesive pad with a release sheet having this configuration (Figs. 1-4). Smith Ind. Pub. Lim. Co. teaches this release sheet configuration provides a means to avoid adhesive contact with the fingers so that the adhesive will not become contaminated or lose effectiveness (Col. 4, lines 29-32, Col. 1, lines 17-20, lines 24-33). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the electrode pad of Gliner et al. and Ferrari with a release sheet having the configuration of Smith Ind. Pub. Lim. Co. in order to avoid adhesive contact with the fingers so that the adhesive will not become contaminated and lose effectiveness.

With respect to claims 12, and 22, Gliner et al. shows the electrode pad further comprises a conductive gel associated with each electrode pad (32).

Regarding claims 13-14, and 23- 24, Gliner et al. shows a non-conductive adhesive surrounding the gel (Col. 4, lines 32-36).

With respect to claims 15, and 19, Smith Ind. Pub. Lim. Co. shows the release sheet is folded in a substantially U-shaped configuration (Figs. 1-4).

Regarding claim 17 Gliner et al. shows the defibrillator comprises an automatic external defibrillator.

Regarding claim 20, Smith Ind. Pub. Lim. Co. shows an edge of the second portion of the release sheet extends beyond an adjacent edge of the pad, providing a pull-tab (23, 33) that can be grasped during removal of the release sheet (Fig. 3).

With respect to claim 21, Smith Ind. Pub. Lim. Co. shows the release sheet is configured so that as the release sheet is peeled away, a fold about which the release sheet is folded travels in the direction in which the second portion is pulled (Fig. 3).

***Response to Arguments***

7. Applicant's arguments filed 9/22/03 have been fully considered but they are not persuasive.
8. In response to applicant's argument that the Smith Ind. Pub. Lim. Co. reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the release sheets of Smith Ind. Pub. Lim. Co. and the teaching to use such release sheets to avoid contamination (i.e. grease, dirt, or dust) and tangling with fingers, which reduces the effectiveness of the adhesive, is reasonably pertinent to applicant's problem of applying electrode pads with adhesives to the surface of the body.
9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation for combining the references is to avoid adhesive contact with the fingers so that the adhesive will not become contaminated and lose effectiveness. This motivation is found in the Smith Ind. Pub. Lim. Co. reference.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### *Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drosch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

*Kristen Drosch*

kld

*Kennedy Schaezle*  
KENNEDY SCHAEZLE  
PRIMARY EXAMINER  
11-2-03